



12-17-03

PTO/SB/21 (08-03)

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/612,650	
	Filing Date	July 2, 2003	
	First Named Inventor	S. Megati	
	Art Unit	1645	
	Examiner Name	Not Yet Assigned	
Total Number of Pages in This Submission	8	Attorney Docket Number	WYTH0015-100/AM100961

ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): References AA-BE			
<table border="1"><tr><td>Remarks</td><td rowspan="2">EL964553491US</td></tr><tr><td></td></tr></table>			Remarks	EL964553491US	
Remarks	EL964553491US				

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Michael P. Straher/Reg. No. 38,325
Signature	
Date	December 16, 2003

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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AM100961 (WYTH 0015-100)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: S. Megati, et al.

Serial No.: 10/612,650

Group Art Unit: 1645

Filing Date: July 2, 2003

Examiner: Not Yet Assigned

For: PREPARATION OF
6-HYDROXYEQUILENINS

EXPRESS MAIL INFORMATION

EXPRESS MAIL LABEL NO: EL 964553491 US

DATE OF DEPOSIT: *December 16, 2003*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

This Information Disclosure Statement is being filed:

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☒ **before** the mailing date of a first Office Action on the merits.
- ☐ **after** the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
- ☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);
- or**
- ☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☒ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously with, the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), a Petition requesting consideration of the Information Disclosure Statement and the Petition Fee of \$130.00 set forth in 37 C.F.R. § 1.17(i)(1) (see "Statement," "Petition," and "Fees" below).
- ☒ Copies of references (AA-BE) listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are enclosed herewith

EXCEPT THAT:

- ☐ In view of the voluminous nature of references @@@, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.

- ☐ Copies of references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 were previously cited by or submitted to the U.S. Patent and Trademark Office in parent application Serial No. _____ filed on _____.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Statement under 37 C.F.R. § 1.97(e)

- ☐ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

Petition

- ☐ Applicant(s) hereby petitions the Assistant Commissioner to consider the references listed in this Information Disclosure Statement, on the enclosed PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449, and the examination of the above-identified patent application.

Fees

- ☒ No Fee is owed by the applicant(s).
- ☐ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.
- ☐ The Petition Fee of \$130.00 under 37 C.F.R. § 1.17(i)(1) is enclosed herewith.

Method of Payment of Fees

- ☐ Attached is a check in the amount of \$_____. This form is submitted in duplicate.
- ☐ Charge Deposit Account No. 50-1275 in the amount of \$_____. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.

☒ No fee or Statement is required under 37 C.F.R. § 1.97(b).

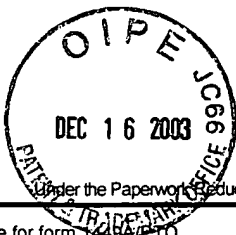
Respectfully submitted,



Michael P. Straher
Registration No. 38,325

Dated: *December 16, 2003*

COZEN O'CONNOR, P.C.
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PTO/SB/08b(05-03)

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

Complete if Known

Application Number	10/612,650
Filing Date	July 2, 2003
First Named Inventor	S. Megati
Group Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	WYTH0015-100/AM100961

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

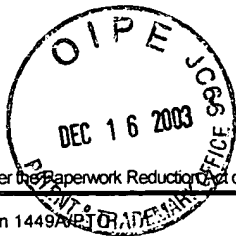
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AA	Mendelsohn and Karas, "The protective effects of estrogen on the cardiovascular system," New Engl. J. Med. (1999) 340:1801-1811.	
	AB	Epperson, et al., "Gonadal steroids treatment of mood disorders," Psychosomatic Med. (1999) 61:676-697.	
	AC	Crandall, J. "Estrogen replacement therapy and colon cancer: a clinical review," Women's Health Gender-Based Med. (1999) 8:1155-1166.	
	AD	Monk and Brodaty, "Us of estrogens for the prevention and treatment of Alzheimer's disease," Dementia & Geriatric Cognitive Disorders (2000) 11:1-10	
	AE	Hurn and Macrae, "Estrogen as a neuroprotectant in stroke," J. Cerebral Blood Flow & Metab. (2000) 20:631-652.	
	AF	Calvin, "Oestrogens and wound healing," Maturitas (2000) 34:195-200.	
	AG	Finking, et al., "The effects of estrogen in the cardiovascular system," Zeitschrift fur Kardiologie (2000) 89:442-453.	
	AH	Brincat, "Hormone replacement therapy and the skin," Maturitas (2000) 35:107-117.	
	AI	Al-Azzawi, "The menopause and its treatment in perspective," Postgrad. Med. J. (2001) 77:292-304.	
	AJ	Moggs and Orphanides, "Estrogen receptors: orchestrators of pleiotropic cellular response," EMBO Reports (2001) 2:775-7781.	
	AK	Hall, et al., "The multifaceted mechanisms of estradiol and estrogen receptor signaling," J. Biol. Chem. (2001) 276:36869-36872.	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 2 of 3

Complete if Known

Application Number	10/612,650
Filing Date	July 2, 2003
First Named Inventor	S. Megati
Group Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	WYTH0015-100/AM100961

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

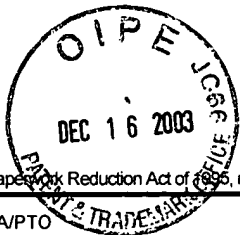
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AL	McDonnell, "The mechanism of action of steroid hormone receptors," in Principles of Molecular Regulation, (2000) pp. 351-361	
	AM	McKenna, et al., "Nuclear receptor coregulators: cellular and molecular biology," Endocrine Rev. (1999) 20:321-344	
	AN	Quaedackers, et al., "4-Hydroxytamoxifen trans-represses nuclear factor kappa-B activity in human osteoblastic U2-OS cells through estrogen receptor (ER)alpha and not through ERbeta," Endocrinol. (2001) 142:1156-1166.	
	AO	Bhat, et al., "A novel estrogen receptor beta: identification and functional analysis of additional N-terminal amino acids," J. Steroid Biochem. Mol. Biol. (1998) 67:233-240.	
	AP	Pelzer, et al., "Estrogen effects in the myocardium: inhibition of NF-kappaB DNA binding by estrogen receptor-alpha and -beta," Biochem. Biophys. Res. Comm. (2001) 286:1153-1157.	
	AQ	Levin, "Cell localization, physiology, and non-genomic actions of estrogen receptors," J. Appl. Physiol. (2001) 91:1860-1867.	
	AR	Levin, "Cellular functions of the plasma membrane estrogen receptor," Trends Endocrinol. Metab. (1999) 10:374-377.	
	AS	Green, et al., "Human oestrogen receptor cDNA: sequence, expression and homology to v-erb-A," Nature (1986) 320:134-139.	
	AT	Kuiper, et al., "Cloning of a novel estrogen receptor expressed in rat prostate and ovary," Proc. Natl. Acad. Sci. USA (1996) 93:5925-5930.	
	AU	Couse, et al., "Tissue distribution and quantitative analysis of estrogen receptor-alpha (ERalpha) and estrogen receptor-beta (ERbeta) messenger ribonucleic acid in the wild-type and ERalpha-knockout mouse," Endocrinol. (1997) 138:4613-4621.	
	AV	Kuiper et al., "Comparison of the ligand binding specificity and transcript tissue distribution of estrogen receptors alpha and beta," Endocrinol. (1997) 138:863-870.	

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 3 of 3

Complete if Known

Application Number	10/612,650
Filing Date	July 2, 2003
First Named Inventor	S. Megati
Group Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	WYTH0015-100/AM139737

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AW	Sar and Welsch, "Differential expression of estrogen receptor-beta and estrogen receptor -alpha in the rat ovary," Endocrinol. (1999) 140:963-971.	
	AX	Fitzpatrick, et al., "Expression of estrogen receptor-beta protein in rodent ovary," Endocrinol. (1999) 140:2581-2591.	
	AY	Cowley, et al., "Estrogen receptors alpha and beta form heterodimers on DNA," J. Biol. Chem. (1997) 272:19858-19862.	
	AZ	McDonnell, J., "Selective estrogen receptor modulators (SERMs): a first step in the development of perfect hormone replacement therapy regimen," Soc. Gynecolog. Invest. (2000) 7:S10-S15.	
	BA	Goldstein, "A pharmacological review of selective oestrogen receptor modulators," Human Reproduction Update (2000) 6:212-224.	
	BB	Pike, et al., "Structure of the ligand-binding domain of oestrogen receptor beta presence of a partial agonist and a full antagonist," EMBO J. (1999) 18:4608-4618.	
	BC	Shiau, et al., "The structural basis of estrogen receptor/coactivator recognition and the antagonism of this interaction by tamoxifen," Cell (1998) 95:927-937.	
	BD	Ogawa, et al., "The complete primary structure of human estrogen receptor beta (hER-beta) and its heterodimerization with ER alpha in vivo and in vitro," Biochem. Biophys. Res. Comm. (1998) 243:122-126.	
	BE	Paige, et al., "Estrogen receptor (ER) modulators each induce distinct conformational changes in ER alpha and ER beta," Proc. Natl. Acad. Sci. USA (1999) 96:3999-4004.	

Examiner
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